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July 16, 2021

VIA ECF

Hon. Michael A. Shipp, U.S.D.J.
U.S. District Court
District of New Jersey
Clarkson S. Fisher Fed. Bldg. & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

Re: Amgen Inc. v. Sandoz, Inc., No. 3:18-cv-11026(MAS)(DEA)(consolidated)

Dear Judge Shipp:

We, along with Covington & Burling LLP, and Sidley Austin LLP, represent Plaintiff Amgen Inc. ("Amgen") in the above-referenced consolidated Hatch-Waxman litigation. We write to respectfully request that the Court strike and disregard Defendants' post-trial citations to, and attorney argument regarding, an FDA Guidance document that is not part of the now-closed record.

In their post-trial brief, Defendants improperly cited to, and purported to interpret, an FDA Guidance for Industry that was not introduced as evidence at trial, was not on the trial exhibit list (i.e., not part of the pre-trial order, see Trial Tr. at 1291:9–10 (The Court) ("The final pretrial order has to have some preclusive effect here.")), was not discussed by any witness at trial, and for which Defendants have not sought judicial notice. (ECF No. 467 at 79 (citing *Guidance for Industry: Development of Abbreviated New Drug Applications During the COVID-19 Pandemic – Questions and Answers* (Apr. 5, 2021).) The time for adding evidence to the record is past. Defendants' belated attempt to expand the record after trial prejudices Amgen, because Amgen cannot cross examine Defendants' expert(s) about the reference, respond with its own expert testimony, or introduce additional references.

The impropriety of Defendants' citation is compounded by Defendants' attorney-argument purporting to interpret and apply the non-record document to the facts in this case. (See ECF No. 467 at 79.) Interpretation of FDA Guidance documents, and applying them to the specific facts of the case, is squarely within the domain of qualified experts, not attorney-advocates.¹ See FRE 702. Amgen respectfully requests the Court to strike and disregard Defendants' attempt to improperly expand the record in post-trial briefing through unqualified attorney-argument using documents outside the trial record.

¹ For example, Defendants introduced other FDA Guidance documents at trial (e.g., DTX-119) and sought testimony about those FDA Guidance documents from their experts. (See, e.g., Trial Tr. at 582:12–15 (Gribble Direct 6.18.21) (discussing DTX-119 (FDA Guidance: Development of New Stereoisomeric Drugs — May 1, 1992))).

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Given the short window of time before closing arguments on July 28, after reviewing the record, we were compelled to promptly alert the Court and request relief from Your Honor. If the Court would prefer, Amgen is prepared to submit a formal motion to strike.

We thank the Court for its consideration and assistance in this matter. If the Court has any questions, we would be pleased to respond to same at the Court's convenience.

Respectfully submitted,

s/ Charles H. Chevalier
Charles H. Chevalier

cc: All counsel of record for Amgen and all Defendants (via ECF and Email)